Hi-Dow® Hi-Dow International, Inc.

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Section 5 - 510(k) Summary

Date of Summary Preparation: 1/17/2011

MAY 13 2011

1. Submitter's Identifications

Submitter's Name: Hi-Dow International, Inc.
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2. Correspondent's Identifications

Correspondent's Name: Hi-Dow International, Inc.
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3. Name of the Device

Device Classification Name:
Stimulator, Muscle, Powered, Over-the-Counter
Product Name: Powered Muscle Stimulator
Trade Name: Hi-Dow
Models: JQ-5C
Classification Panel: Neurology
Product Code: NGX NUH
Device Classification: Class□
Contraindications: None

4. The Predicate Devices

K060846	T1040	TENS	21CFR 882.5890 OTC
K033122	Prizm Medical Inc.	5000Z OTC TENS	21CFR 882.5890 OTC
K01 1880	Compex Sport	Sport Muscle Stimulator	21CFR 890.5850 OTC

5. Device Description

The JQ-5C is a portable; battery powered (3.7VDC) multi function device offering both Transcutaneous Electrical Nerve Stimulator (TENS) and Powered Muscle Stimulator (PMS)

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qualities in one device.
Double channels that effectively transfers your desired choice of programmed electrical pulses directly through electrode adhesive pads to the suggested area of the body where the electrodes are placed, causing minimal muscle contractions. There are 6 modes of operation.

6. Intended Use of Device

TENS:

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

PMS:
It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

7. Summary of Substantial Equivalence

Table : The difference between JQ-5C and Predicate T1040、5000Z and Compex.

Quantity	JQ-5C	T1040	5000Z	Compex
Max Voltage over 10k , V	84	154.1	226	126.8/103.3
Max. Current over 10k ,mA	8.4	15.4	22.6	12.7/10.3
Max. Voltage over 2.2k, V	79.2	105.1	218	167.8/153.5
Max. Current over 2.2k , mA	39.6	47.8	99	76.3/69.8
Max. Voltage over 500 , V	62.4	40.7	208	48
Max. Current over 500 , mA	124.8	81.4	416	96.1
Pulse Width, μ seconds	100	210	100	270
Pulse Period, msec	16.3~781	4.1-500	10	125
Max. Pulse Frequency, Hz	61.3	245	120	118
Max Charge per Phase over 500Ω, μC	17.92	16.9	3.4	32.3
Max Current Density over 500Ω, mA/cm2	9.92	2.71	16.64	3.84
Max. Average Power Density over 500 Ω,mWcm2	2.72	5.35		10.2

8. Substantial Equivalence:

The electrical stimulation provided by the JQ-5C is substantially equivalent to that commonly employed by muscle stimulators and TENS devices that have been cleared for marketing without prescription labeling; i.e, for OTC sale. The pulses in the waveform combinations are restricted

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in amplitude and duration to values consistent with the other device quoted above.
Technological characteristics, features, specifications, materials and intended uses of the JQ-5C are substantially equivalent to the quoted predicate device.
The differences that exist between the devices are insignificant in the terms of safety or effectiveness.
The JQ-5C has modes that offer substantially equivalent technical specifications, features and effective results as the predicate listed.

9. Non-Clinical Tests Performed:

Compliance to applicable voluntary standards include: the Council Directive 93/42/EEC, as well as EN60601-1, EN60601-1-2, EN ISO 14971:2009, EN ISO 10993-1:2009, EN 60601-2-10:2000 + A1:2001 ~~and EN 60601-1-4:1996+A1:1999~~.
In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

10. Conclusion:

The electrical stimulation provided by the JQ-5C is similar to the commonly employed muscle stimulators and TENS devices that have been cleared for marketing without prescription labeling.

The JQ-5C has the same intended uses and the similar technological characteristics as this OTC predicate. Moreover, verification and validation tests contained in this submission demonstrate that the differences in JQ-5C still maintain the same safety and effectiveness as that of the cleared device.

In other words, those engineering differences do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

Concerns of safe and proper use of electrodes and electrode pad placement have been fully addressed by making the user conscious of the proper placement of the electrodes and proper operations of the device through detail in the User's Instruction Manual.

We believe that there are no new safety or effectiveness issues concerning this device to be introduced.

The safety of the device, to be used for the proposed indications without medical prescriptions or supervision, is established by the fact that no adverse events have been reported sine 2007 with over 300,000 units sold without a prescription in Europe and Asia.

Over 300,000 units sold with no adverse effects reported, proves its specific technical, safety measures and features are safe and effective when used without medical supervision.

The effectiveness of the device for the proposed indications is supported by a number of articles in peer-reviewed publications, which demonstrate that electrical stimulation does improve muscle performance as well as temporary pain reduction.

Technological characteristics, features, specifications, materials and intended uses of the JQ-5C are substantially equivalent to the quoted predicate device.

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The differences that exist between the devices are insignificant in the terms of safety or effectiveness.

The JQ-5C has modes that offer substantially equivalent technical specifications, features and effective results as the predicate listed.

--- End of this section ---

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Hi-Dow International Inc
% Mr. Eric Chen
2071 Congressional Drive
St Louis, Missouri 63146

MAY 13 2011

Re: K102598
Trade/Device Name: Hi-Dow Model JQ-5C
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: April 27, 2011
Received: May 4, 2011

Dear Mr Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may; therefore, market the device subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section 4 - Indications for Use

510(k) Number (if known): K102598

Device Name: Powered Muscle Stimulator
Models: JQ-5C

Indications for Use:

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K102598